DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 13, 2015

Inmode Md Ltd.
% Ahava Stein
Regulatory Manager
A. Stein-Regulatory Affairs Consulting Ltd.
20 Hata'as Str., Suite 102
Kfar Saba, 4442520
Israel

Re: K142952
Trade/Device Name: Inmode Diolaze Device
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: November 19, 2014
Received: November 24, 2014

Dear Ahava Stein,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142952

Device Name
InMode Diolaze Device

Indications for Use *(Describe)*
The InMode Diolaze device is indicated for use for hair removal and for permanent reduction in hair regrowth, defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

INMODE DIOLAZE DEVICE

510(k) Number K 142952

Applicant Name:

Company Name: InMode MD Ltd.
Address: Tabor Building, Shaar Yokneam
Yokneam 2069200
Israel
Tel: +972-4-9097470
Fax: +972-4-9097471
E-mail: ahava@asteinrac.com

Contact Person:

Official Correspondent: Ahava Stein
Company Name: A. Stein – Regulatory Affairs Consulting Ltd.
Address: 20 Hata'as Str., Suite 102
Kfar Saba 4442500
Israel
Tel: +972-9-7670002
Fax: +972-9-7668534
E-mail: ahava@asteinrac.com

Date Prepared: October 07, 2014

Trade Name: InMode Diolaze Device

Classification Name: CFR Classification section 878.4810; (Product code GEX)

Classification: Class II Medical Device

Predicate Device:

The InMode Diolaze device is substantially equivalent to the following predicate devices.

Manufacturer	Device	510(k) No.
InMode MD Ltd.	InMode Hair Removal (HR) Device	K123682
Quantel Derma GmbH	Leda EPI 808	K090762

Device Description:

The InMode Diolaze device is designed to deliver optical energy to the skin via a pre-cooled sapphire block. The good optical contact between the sapphire block and skin is achieved by using water based gel. The device provides individual adjustment of light fluence and pulse duration to achieve maximum efficiency and safety for each patient. The scanning system embedded into the laser of the InMode Diolaze device hand piece allows efficient treatment with less risk of overlap. The hand piece has integrated skin cooling to enhance safety and comfort of the treatment.

The InMode Diolaze device consists of an AC/DC power supply unit, a diode driver, water cooling system, controller and user interface including an LCD screen and functional buttons. The diode laser hand piece is connected to the console via a cable and a foot switch activates the energy delivery to the hand piece. The hand piece comprises the InMode Diolaze device laser with linear scanning system, cooled sapphire output window (8 x 50mm), and electronic shutter.

The sapphire light guide is located on the front tip of the hand piece and delivers the laser beam energy to the treated tissue, while cooling the skin. The pair of thermoelectric coolers (TECs) located on both sides of the sapphire block provide cooling to a temperature of 4^{o}C. The hand piece contains a trigger button which starts the laser scan and radiation. Fluence (light energy density) is delivered within the limits of 10 to 60J/cm^{2}. The hand piece has a cable that is 170cm long and connects the hand piece to the console via a connector.

Intended Use/Indication for Use:

The InMode Diolaze device is indicated for use for hair removal and for permanent reduction in hair regrowth, defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

Performance Standards:

The InMode Diolaze device is identical to the InMode Hair Removal (HR) device (same device). Therefore, the InMode Diolaze device complies with the voluntary performance standards listed below in which the InMode Hair Removal (HR) device was tested and complies with:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995
- IEC 60601-1-2, (Third Edition, 2007), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests
- IEC 60825-1 - Safety of laser products, Part 1: Equipment classification and requirements; (2001)

- IEC 60601-2-22 – Medical Electrical Equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment (1995)

Non-Clinical Performance Data:

The InMode Diolaze device is identical to the InMode Hair Removal (HR) device (same device), as such, for this 510k submission the same performance test documents used for K123682 are provided comparing the InMode Hair Removal (HR) device laser output parameters to those of the Leda EPI 808 predicate device. The results of the bench tests demonstrate that the InMode HR device has the same laser output specifications as the predicate Leda EPI 808 device and along with the fact that the InMode Diolaze device is identical to the InMode Hair Removal device, it can be concluded that the InMode Diolaze device is substantially equivalent to the predicate devices.

Clinical Performance Data:

Not Applicable

Substantial Equivalence:

The indications for use of the InMode Diolaze device are substantially equivalent to the indications for use of the Leda EPI 808 predicate device and are an expansion of the indications for use of the InMode Hair Removal (HR) device with the permanent reduction in hair regrowth indication. The design and components in the InMode Diolaze device, including the console (with power supply, software, cooling system and touch screen user interface), the water-cooled hand piece (with cable and connector to console) and the foot switch are identical to the design and components found in the InMode Hair Removal (HR) (same device) and similar to the Leda EPI 808 predicate devices. The performance specifications (including wavelength, fluence, pulse width, pulse repetition rate, spot size and cooling) in the InMode Diolaze device are identical to performance specifications in the InMode Hair Removal (HR) and similar to the Leda EPI 808 predicate device. The safety features in the InMode Diolaze device are substantially equivalent to the safety features found in the predicate devices. Consequently, the InMode Diolaze device is substantially equivalent to the InMode Hair Removal (HR) predicate device, cleared in 510(k) K123682, and to the Leda EPI 808 predicate device, cleared in 510(k) K090762, and therefore, may be legally marketed in the USA.

Conclusions:

Based on the performance testing and comparison to predicate devices, the InMode Diolaze device is substantially equivalent to the predicate devices listed above.